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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,094	04/18/2000	Scott E. Anderson	38-21(15503)B	4263

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EXAMINER
MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	8

DATE MAILED: 01/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/553,094	ANDERSON ET AL.	
	Examiner	Art Unit	
	Marjorie Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) 2-7 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). 7 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Applicant's election with traverse of Group I, claim 1, and SEQ ID NO: 1 in Paper No. 5, filed 8/27/01, is acknowledged. The traversal is on the ground(s) that the nucleic acids of Group I are related to the proteins of Group II, and that it would not be an undue burden to search both Groups or to search at least ten nucleotide sequences. This is not found persuasive because, as previously set forth in the restriction requirement, polypeptides and polynucleotides are different biochemical entities with different structures and properties, and would be expected to behave differently in methods of use. As Group I is directed to different products than is Group II, the examiner maintains that the restriction is proper. In response to the argument that a search more than one Group or a search for at least ten nucleotide sequences would not be an undue burden, it is noted that a search for any Group or sequence requires a search of nonpatent literature and foreign patents as well as US patents. In addition, a search for a polypeptide sequence requires a search of databases not required for a search for a polynucleotide sequence; and a search for a polynucleotide does not necessarily include a search for peptides encoded thereby. Also, due to the increasing number of applications requiring sequence searches and the increasingly large databases which must be searched, it now constitutes an undue burden on the Office to search more than a single sequence per application. For these reasons, the examiner maintains that it would be an undue burden to search and examine more than a single Group and more than a single nucleotide sequence.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-7 and all sequences other than SEQ ID NO: 1 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions, there

being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

An action on the merits of claim 1, as it reads on SEQ ID NO: 1, follows.

Information Disclosure Statement

The IDS filed 4/18/00 has been fully considered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See pages 5 and 28 of the instant specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, □Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 1 is rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification teaches on page 7 that the inventive sequences may be used for comparative sequence analysis or to identify sequence motifs. However, these are general utilities applicable to any polynucleotide sequence and are not specific to elected SEQ ID NO: 1. The instant specification does not disclose any sequence motif specific to SEQ ID NO: 1, nor whether SEQ ID NO: 1 comprises a sequence motif correlated to a known function. For example, a motif known to be present in every member of a protein family may be used to identify other members of the family; or a motif may be known to encode the active site of a particular class of enzymes. It is noted that establishing such a correlation constitutes further research on the sequence itself. Identification of a sequence motif of unknown function or which is not known to be correlated to a known function does not constitute a specific,

substantial and credible utility, therefore SEQ ID NO: 1 does not have utility based on identification of a sequence motif.

The specification discloses on pages 10-15 that the inventive polynucleotides may be used to transform plants, to determine associations with polymorphic sites, to determine a level or pattern of protein expression, to detect mutations, or to reduce protein expression. The specification further discloses on pages 33-74 that the inventive polynucleotides may be used to obtain other nucleic acid sequences, to identify mutations and polymorphisms, may be used in genetic mapping and in protein expression assays, and may be used as molecular markers. These are all general uses applicable to any nucleic acid sequence and are not specific to elected SEQ ID NO: 1. Any polynucleotide may be used to transform a plant; the results and usefulness of the transformed plant depend on the polynucleotide sequence used; e.g. a particular sequence may cause faster growth, enhanced microbial or insect resistance, etc. A transformed plant may also be used to generate large amounts of a product (e.g. a peptide encoded by a polynucleotide); however, a use to make something of unknown utility does not confer utility to the "starting material" (polynucleotide), nor to the method itself. The instant specification does not disclose any particular function related to SEQ ID NO: 1, or its transcription or translation, nor does the specification disclose a function for any peptide encoded by SEQ ID NO: 1, therefore a utility to transform a plant is not a specific, substantial and credible utility for SEQ ID NO: 1.

With regard to polymorphic sites, the specification does not teach that SEQ ID NO: 1 comprises with a polymorphic site. With regard to mutation detection, the specification does not teach any particular function associated with SEQ ID NO: 1 nor for any peptide which may be encoded by SEQ ID NO: 1, as set forth above. The specification does not disclose any nexus between SEQ ID NO: 1 or expression thereof and a known characteristic (e.g. faster

growth, change in susceptibility to a disease) wherein detection of a mutation associated with SEQ ID NO: 1 would provide useful, "real-world" information regarding that characteristic. Detection of a mutation associated with SEQ ID NO: 1 may be of scientific interest, but further research would be required to determine what affect (if any) the mutation has and/or determine an association (if any) to a particular characteristic of the organism in which the mutation is detected. For the reasons set forth above, the utilities set forth with regard to detection of polymorphisms and mutations are not specific, substantial and credible for SEQ ID NO: 1.

With regard to reduction of protein expression, the specification fails to disclose that any inventive polynucleotide sequence, specifically SEQ ID NO: 1, actually encodes a protein, or is involved in protein synthesis. The instant specification does not disclose any polypeptide sequences anywhere. The specification does not teach any open reading frame (defined by start and stop codons) for SEQ ID NO: 1. SEQ ID NO: 1 comprises at least four potential start codons; the specification does not set forth a utility or function for any peptide putatively encoded in any reading frame by SEQ ID NO: 1. The instant specification does not disclose any function for SEQ ID NO: 1 itself with regard to protein synthesis (e.g. as a regulatory element). As neither the specification nor the prior art teaches a function for SEQ ID NO: 1 or for any protein encoded thereby, utility with regard to reducing protein expression is not a specific, substantial and credible utility, nor a well-established utility for SEQ ID NO: 1.

A use to obtain other nucleic acid sequences and a use as a molecular marker are also general uses applicable to any nucleic acid sequence and are not specific to SEQ ID NO: 1. With regard to genetic mapping, a sequence may have specific, substantial and credible utility if the sequence or site mapped were associated with a known disease, phenotype, etc. Mapping a sequence to an unknown site with unknown function is not a specific, substantial and credible utility. No association with a disease, phenotypic characteristic, etc. is disclosed in the instant

specification for SEQ ID NO: 1, therefore none of genetic mapping, use to obtain other nucleic acids, and a use as a molecular marker is a specific, substantial and credible utility for SEQ ID NO: 1.

A polynucleotide may have utility where it encodes a protein which has a specific, substantial and credible utility, or a well-established utility. For example, insulin has a well-known utility, therefore a polynucleotide sequence encoding insulin would have a well-established utility. Claim 1 is drawn to a polynucleotide "that encodes a maize protein of fragment thereof"; however, the specification does not disclose any protein actually encoded by SEQ ID NO: 1. SEQ ID NO: 1 comprises at least four potential start codons; the specification fails to disclose a utility or function for any peptide putatively or possibly encoded by SEQ ID NO: 1. The prior art does not teach an established utility for any peptide encoded by SEQ ID NO: 1, therefore SEQ ID NO: 1 does not have specific, substantial and credible utility, or a well-established utility based on the utility of an encoded polypeptide.

For all of the reasons set forth above, SEQ ID NO: 1 does not have a specific, substantial and credible utility, or a well-established utility.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

35 U.S.C. 112, Written Description Rejection

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a polynucleotide sequence "that encodes a maize protein or fragment thereof"; however, the instant specification does not disclose that SEQ ID NO: 1 actually encodes any protein, nor that a protein encoded must be specific to maize. SEQ ID NO: 1 comprises at least four start codons; however, the specification does not disclose any particular open reading frame encoding a polypeptide. The specification does not disclose any polypeptide sequences anywhere, nor does the specification disclose that any polypeptide sequence putatively encoded by SEQ ID NO: 1 MUST be a maize protein. In fact, the specification discloses on pages 20-21 that the proteins encoded by the inventive polynucleotide sequences may be homologous to proteins from other organisms such as other plants or fungi, wherein a homologue may be 25-100% identical to peptides encoded by the inventive nucleotide sequences. The inventive nucleotide sequences, although obtained from a maize library, may therefore encode non-maize proteins. The instant specification fails to teach that SEQ ID NO: 1 encodes any polypeptide, specifically a maize protein, therefore claim 1 is rejected for lack of sufficient written description.

Conclusion

Claim 1 is rejected; claims 2-7 are withdrawn. The specification is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Marjorie A. Moran
Examiner
Art Unit 1631

January 16, 2002